EXHIBIT AF

JEFFREY I. WEINBERGER (SBN 056214)
jeffrey.weinberger@mto.com
TED G. DANE (SBN 143195)
ted.dane@mto.com
HEATHER E. TAKAHASHI (SBN 245845)
heather.takahashi@mto.com
MUNGER, TOLLES & OLSON LLP
355 South Grand Avenue, 35th Floor
Los Angeles, CA 90071-1560
Telephone: (213) 683-9100
Facsimile: (213) 687-3702

Attorneys for Plaintiffs
TAKEDA PHARMACEUTICAL CO., LTD., TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., TAKEDA PHARMACEUTICALS LLC, AND TAKEDA PHARMACEUTICALS AMERICA, INC.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

TAKEDA PHARMACEUTICAL CO., LTD., TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., TAKEDA PHARMACEUTICALS LLC, AND TAKEDA PHARMACEUTICALS AMERICA, INC., Plaintiffs, v. HANDA PHARMACEUTICALS, LLC, Defendant.	Case No. 3:11-cv-00840 JCS **DECLARATION OF ALLAN S. MYERSON, PH.D., IN SUPPORT OF TAKEDA'S OPENING CLAIM CONSTRUCTION BRIEF** Date: February 16, 2012 Time: 9:30 a.m. Judge: Hon. Joseph C. Spero Courtroom G, 15th Floor
TAKEDA PHARMACEUTICAL CO., LTD., TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., TAKEDA PHARMACEUTICALS LLC, AND TAKEDA PHARMACEUTICALS AMERICA, INC., Plaintiffs, v. ANCHEN PHARMACEUTICALS, INC., AND TWI PHARMACEUTICALS, INC., Defendants.	Case No. 3:11-cv-01609 JCS

TAKEDA PHARMACEUTICAL CO., LTD., TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., TAKEDA PHARMACEUTICALS LLC, AND TAKEDA PHARMACEUTICALS AMERICA, INC., Plaintiffs, v. IMPAX LABORATORIES, INC., Defendant.	Case No. 3:11-cv-01610 JCS

I, Allan S. Myerson, declare as follows:

1. I am currently Professor of the Practice of Chemical Engineering at the Massachusetts Institute of Technology ("MIT") in Cambridge, Massachusetts. I submit this declaration in support of the opening claim construction brief submitted by Plaintiffs Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals North America, Inc., Takeda Pharmaceuticals LLC, and Takeda Pharmaceuticals America, Inc. (collectively, "Takeda"). In particular, I submit this declaration (a) to provide relevant background information regarding the technology at issue in U.S. Patent Nos. 6,462,058 (the "'058 patent"), 6,664,276 (the "'276 patent"), 6,939,971 (the "'971 patent"), and 7,285,668 (the '668 patent") (collectively, the "crystal-form patents"), and U.S. Patent No. 7,737,282 (the "'282 patent") (the "amorphous-form patent"),[1] and (b) to set forth my opinions about the meanings of certain disputed claim terms in these patents from the perspective of a person of ordinary skill in the pertinent field at the relevant times.

I. QUALIFICATIONS

2. The following is a brief summary of my background and qualifications. My background and qualifications are more fully set out in my curriculum vitae, attached as Exhibit 6.

[1] Copies of the crystal-form patents are attached as Exhibits 1, 2, 3, and 4 respectively. A copy of the amorphous-form patent is attached as Exhibit 5.

Exhibit	Reference	Relevant Definition
27	James E. Brady and Fred Senese, *Chemistry: Matter and Its Changes,* G-1 (4th ed. 2004) (DEX0014489–91), at DEX0014491.	defining "amorphous solid" as "[a] noncrystalline solid"
14	Hsien-Hsin Tung et al., *Crystallization of Organic Compounds: An Industrial Perspective* 25 (2009) (DEX0014717-723), at DEX0014719.	"Amorphous materials are solids in which molecules do not have a periodical three-dimensional pattern."

82. The person of ordinary skill reading the specification and claims of the '282 patent would understand the term "amorphous compound" to refer to an amorphous solid, for several reasons.

83. First, the specification provides two examples of what it describes as an "amorphous substance": the product of Reference Example 1 and the product of Reference Example 2. Reference Examples 1 and 2 describe the isolation of optically pure dexlansoprazole from a starting material consisting of racemic lansoprazole (containing both the right and left enantiomers). The specification states that the isolated dexlansoprazole was "evaporated to dryness to yield R(+)-lansoprazole . . . as an amorphous substance." '282 patent, col.8, ll.3-6; '282 col.8, ll.25-29. This reference to drying the amorphous substance indicates that the amorphous substance was in a solid form.

84. In addition, Experimental Example 2 goes on to compare the stability of the amorphous form of dexlansoprazole to the crystal form:

> The crystals of R(+)-lansoprazole as obtained in Example 2 (about 5 mg) and amorphous R(+)-lansoprazole as obtained in Reference Example 1 (about 5 mg) were each taken in a colorless glass bottle, and their stability during storage at 60° C. (stopper removed) was examined. A 25 ml solution (concentration: about 0.2 mg/ml) of the sample after completion of storage in the mobile phase, along with a standard solution prepared using the initial lot, was analyzed under the HPLC conditions shown below, and the R(+)-lansoprazole content (residual percentage) was calculated from the peak area obtained. . . .
>
> When the sample was stored at 60° C. (exposed), the crystal of Example 2 retained a content exceeding 90% for up to 4 weeks, whereas the amorphous form of Reference Example 1 showed reduction in content to 70.8% after 1 week and 57.5% after 2 weeks. This finding demonstrates that the crystal of R(+)-

> lansoprazole is more stable and more preferable for use as a pharmaceutical etc. than the amorphous form.

Id., col.14, ll.4-14, 41-47. Crystals are solid substances. One skilled in the art would understand that a stability test comparing an amorphous compound to a crystalline compound would involve a comparison of like to like, namely two solid compounds. Thus, a person of ordinary skill reviewing the patent would understand the inventors' choice of the terms "amorphous compound" and "amorphous substance" instead of "liquid" or "oil" signifies that the amorphous substance referred to is a solid.

85. Because the specification contrasts the "amorphous" dexlansoprazole substance with the "crystal" compound, it is my opinion that the person of ordinary skill would construe the term "amorphous compound" to mean "a non-crystalline solid that lacks the long-range order characteristic of a crystal."

X. CONCLUSIONS

86. To summarize, my opinions are as follows:

A. The terms "a crystal of" and "a crystalline compound of," as those terms are used in the crystal-form patents, mean "a regularly repeating pattern of molecules with long range order extending in three dimensions."

B. The term "characteristic peaks at interplanar spacings (d)," as that term is used in the '058 and '971 patents, means "a series of peaks that are characteristic of a particular crystal form within normal experimental error of X-ray powder diffraction."

C. The term "melting start temperature," as that term is used in the '668 patent, is not indefinite, as one skilled in the art could discern the boundaries of the claim based on the claim language, the specification, and his own knowledge. In my opinion, the phrase "melting start temperature" means "the temperature at which crystals start to melt, represented by the onset temperature of melting as measured by differential scanning calorimetry."

D. A person of ordinary skill in the art of the crystal-form patents would understand the plain and ordinary meaning of the claim term "about," as that term is used in claims 9 and 10 of the '668 patent, to mean "approximately."

E. The term "amorphous compound," as that term is used in the '282 patent, means "a non-crystalline solid that lacks the long-range order characteristic of a crystal."

87. I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Executed on November 4, 2011, at Cambridge MA.

Allan S. Myerson